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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,547	03/23/2000	Randall S. Kent	JAO 28796.02	3851

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EXAMINER
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MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/533,547

Applicant(s)

KENT ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 197-205,222-229 and 232-246 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 197-205,222-229 and 232-246 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 032006
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections – 35 USC §112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 197, 245, and 246 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the above claims now require “wherein a proteinaceous material is not added to the tissue.” These amendments introduce new matter into the claims because it has been held that any negative limitation or exclusionary provisions must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393, (Bd. App. 1983). The mere absence of a positive recitation in a claim is not a basis for an exclusion recitation.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 197-204, 224-229, 232, 234-237, and 243-246 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. ("Sterilisation of Canine Anterior Cruciate Allografts By Gamma Irradiation in Argon") in view of Livesey et al. (U.S. 5,336,616).

With respect to claims 197-204, 227-229, 232, 234-237, and 243-246, Goertzen et al. teaches a method of sterilizing bone anterior cruciate ligament (ACL) - bone allografts with gamma radiation at a total dose of 2.5 Mrad (25 kGy). The allograft is deep-frozen to -80 °C ("about 78 °C") and maintained in an argon gas environment during irradiation. See Abstract; page 206, first full paragraph and last paragraph. Goertzen et al. does not disclose contacting the allografts with a stabilizer.

Livesey et al. discloses that when freezing a tissue, it is necessary to first contact the tissue with a stabilizer (cryoprotectant) in order to protect the tissue by reducing the rate of cooling and/or the freezing point and to reduce hypoxic damage to the tissue. See col.11, lines 55-60. Suitable cryoprotectants include DMSO, polyethylene glycol, propylene glycol, trehalose, and mannitol. See col.8, lines 1-10; col.11, line 49 to col.12, line 30; col.14, lines 36-54; col.16, lines 9-10. The compositions illustrated in col.16, lines 30-50, all use DMSO at 0.5 M. VS2 also includes trehalose. Livesey et al. further discloses that "[o]ptimum pH and buffering capacity against the products of hypoxia damage...is essential." See col.8, lines 67-68.

It would have been obvious to one of ordinary skill in the art to contact the ACL allografts of Goertzen et al. with the cryoprotectant composition of Livesey et al. because the grafts of Goertzen et al. are frozen before irradiation and because the cryoprotectants of Livesey et al. are disclosed to be capable of preserving cell and tissue structure against injury associated with freezing. When frozen, the tissue would intrinsically contain both aqueous, naturally

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occurring solvents and non-aqueous solvents (e.g. propylene glycol, polyethylene glycol) incorporated as cryoprotectants.

As to claims 224-226, Livesey et al. discloses concentrations of 0.5 M for DMSO and 6% for trehalose. See VS2, col.16, lines 30-40. Regardless, it is deemed obvious to optimize the concentration of trehalose based upon routine experimental results.

5. Claims 205 and 238-242 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 204 and 234 above, and further in view of Peterson (U.S. Patent No. 5,730,933).

With respect to claim 205, Goertzen et al. teaches maintaining the tissue in an inert (argon) atmosphere during irradiation but fails to teach vacuum. However, Peterson discloses doing both during irradiation of a tissue. See col.5, lines 28-35. As the removal of air from the environment (a vacuum) will reduce the presence of oxygen and thus, the production of damaging free radicals during irradiation just as in inert atmosphere does, it would have been obvious to do the same in the method of Goertzen et al. with Livesey et al..

As to claims 238-242, Goertzen et al. is silent with respect to lyophilizing the tissue before irradiation. Peterson teaches lyophilization of tissue before irradiation as a means by which to reduce the presence of damaging free radicals due to water in the tissue. See col.5, lines 53-67. For this reason, it would have been obvious to lyophilize the tissue of Goertzen et al. before irradiation thereof and to remove the water to a desired level.

6. Claim 222 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 125 above, and further in view of Chanderkar et al.

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(“The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation”).

Goertzen et al. is silent with respect to the dose rate at which to sterilize the ACL allografts. Chanderkar et al. teaches sterilization of a biological material (fibrinogen) using gamma radiation having a dose rate of 12,500 R/min (7.5 kGy/hr). See page 283-284. It would have been obvious to use the dose rate disclosed by Chanderkar et al. in the method of Goertzen et al., as this dose rate has been shown by Chanderkar et al. to be safe and effective in the sterilization of a biological material.

7. Claim 223 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 197 above, and further in view of Salehpour et al. (“Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts”).

The dose employed by Goertzen et al. is 25 kGy. Salehpour et al., however evidences that a dose this low is insufficient to remove all HIV from the allografts and that in fact, doses higher than 30 kGy may be necessary. See page 898, second paragraph. Therefore, in order to assure complete destruction of all HIV and other pathogens in the allograft of Goertzen et al., it would have been obvious to irradiate the allograft at doses higher than 30 kGy, as determined by routine PCR testing.

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8. Claim 233 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goertzen et al. in view of Livesey et al. as applied to claim 197 above, and further in view of Horowitz et al. (U.S. Patent No. 5,712,086).

Goertzen et al. with Livesey et al. fail to disclose adding a sensitizer to the biological material before irradiation. Horowitz et al. teaches sterilizing biological material wherein a sensitizer (purpurins, phthalocyanines, psoralens, etc.) may be added before irradiation. See col.6, line 64 to col.7, line 10. Horowitz et al. discloses that the use of a sensitizer achieves preferential damage to the virus, but not to the biological material. For this reason, it would have been obvious to add a sensitizer in the method of Goertzen et al. with Livesey et al..

#### ***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


#### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
12 June 2006